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RUSSEL, S

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ART UNIT PAPER NUMBER

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1811

DATE MAILED: 04/25/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 3-13-1995 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1. Claims 1-9 and 22-24 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 10-21 have been cancelled.

3. Claims _____ are allowed.

4. Claims 1-9 and 22-24 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

EXAMINER'S ACTION

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1. The use of the trademark "Pemulen" has been noted in this application. See especially page 7, line 31. It should be capitalized and placed between quotation marks wherever it appears and be accompanied by the generic terminology. See MPEP 608.01(v).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed. Claim 22 does not require the presence of Polysorbate 80; however, the original disclosure requires the presence of Polysorbate 80 in all of Applicants' emulsions. Applicants have not pointed out where the specification supports emulsions which do not contain Polysorbate 80. Claims 22 and 23 recite that glyceride be present in the emulsions. However, the specification does not recite that glycerides in general can be present in the emulsions; rather, the specification is limited to higher fatty

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acid glycerides. It may be that in claims 22 and 23, "glyceride" is a misspelling of "glycerine".

Claims 22 and 23 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

2. Claims 1-4, 9, and 22-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been amended to require the trademarked product "Pemulen" in the composition. However, as the composition of trademarked products can change over time, the use of the trademark in the claims is indefinite in the absence of a fixed and definite meaning of the trademark in the specification. A fixed and definite meaning for the trademarked product "Pemulen" needs to be inserted into the specification, and prior art publications showing that the trademark "Pemulen" has the definition inserted into the specification need to be submitted in order to avoid a new matter objection. See MPEP 608.01(v). There is no antecedent basis in the claims for the phrase "the polysorbate 80" in claim 23, line 6. Note that independent claim 22 does not require the presence of Polysorbate 80.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claims 5-8 are rejected under 35 U.S.C. 103 as being obvious over Hewitt et al in view of Hackh's Chemical Dictionary, and further in view of Kaswan. Hewitt et al teach pharmaceutical compositions comprising 0.2-25% cyclosporin A, 5-60% or 5-80% olive oil, and 0.2-20% polysorbate-80. See, e.g., column 4, lines 16-39. Hackh's Chemical Dictionary teaches that olive oil is inherently comprised of higher fatty acid glycerides, e.g., olein and palmitin. Hewitt et al do not teach the use of castor oil in their compositions, although Hewitt et al disclose generally the use of solvents, diluents, and carriers such as olive oil, mineral oils, petroleum derivatives, and cetyl and steryl alcohols (see, e.g., claim 7). Kaswan discloses that castor oil is a known pharmaceutically acceptable excipient for use in cyclosporins and is functionally equivalent to olive oil, mineral oil, petroleum jelly, and alcohol excipients. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use as the pharmaceutical carrier of Hewitt et al and to substitute for the olive oil component of Hewitt et al's specific compositions the castor oil excipient disclosed by Kaswan, because Hewitt et al's cyclosporin-containing compositions are not limited to any specific solvents, diluents, and carriers, because Kaswan discloses castor oil to be a known excipient for cyclosporin-containing compositions, and because it would have been prima

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facie obvious to substitute known functionally equivalent components, i.e. olive oil and castor oil, for one another.

5. Applicant's arguments filed March 13, 1995 have been fully considered but they are not deemed to be persuasive.

The rejection of claims 5-8 has been maintained. Claims 5-8 are not dependent upon claim 1 and therefore do not require the presence of "Pemulen". The claims would become novel and unobvious over the prior art of record if they were amended to require the presence of "Pemulen", but they would then be subject to the rejection under 35 U.S.C. 112, second paragraph, concerning the use of the trademark in the claims.

6. Claims 1-4, 9, and 22-24 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112. While polyacrylates are used in cosmetic emulsions, there is no motivation to combine "Pemulen" with cyclosporin-containing emulsions which additionally comprise a higher fatty acid glyceride and polysorbate 80.

7. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE

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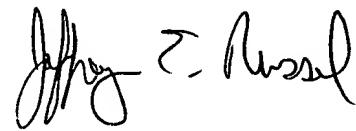
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ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703) 308-4037. The fax number for Art Unit 1811 is (703) 305-7362 and the telephone number for the Group 180 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1811

JRussel
April 23, 1995